EXPEDITED PROCEDURE REQUESTED
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Elledge et al.	)	Examiner: James S. Ketter
USSN: 09/122,384	)	Art Unit: 1636
For: Rapid Subcloning Using Site-Specific Recombination	)	Filed: July 24, 1998

PROTEST AGAINST PENDING APPLICATION UNDER 37 C.F.R. § 1.291

Honorable Commissioner for Patents
Mail Stop Petitions
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Clontech Laboratories, Inc. ("Clontech") hereby petitions the Commissioner to initiate a protest against pending application number 09/122,384 under 37 C.F.R. § 1.291.

I. SUBJECT MATTER DISCLOSED IN U.S. SERIAL NO. 09/122,384 IS THE SUBJECT MATTER OF LITIGATION

Clontech is in litigation against BCM Technologies, Inc. and Baylor College of Medicine (collectively "BCM"), who are believed to be the assignee of USSN 09/122,384 ("the '384 application") over an alleged theft of trade secrets. The case is in the Texas 133rd Judicial District Court in Harris County, Texas, Cause No. 2001-61352.

Clontech repeatedly requested all documents concerning U.S. Patent No. 5,851,808 ("the '808 patent"), the patent that issued from the parent application to the '384 application, which document requests encompass any continuations and continuations-in-part thereof. Clontech

again explicitly requested all documents related to any continuation applications following the April 14, 2003 deposition of Charles Lipsey (the April 14, 2003 letter requesting such documents is attached as Ex. 1 hereto), during which BCM's questioning implied that one or more continuation applications may be pending. BCM has repeatedly ignored such demands and failed to provide such documents until recently, after the close of discovery in the pending litigation. BCM's conduct is the subject of a motion to compel in the Texas Court.

On May 6, 2003, after the close of discovery, litigation counsel for BCM belatedly provided a letter to Clontech enclosing a Notice of Allowability of USSN 09/122,384, which was mailed in late April (Ex. 2 hereto). BCM also provided other documents to Clontech on May 16 and 17, 2003, indicating information disclosed to the Office.

The information BCM provided to Clontech does not indicate that BCM alerted the Office to the case *Baylor College of Medicine et al. v. Clontech Laboratories, Inc. v. Invitrogen Corp.* case in the Texas 133rd Judicial Court in Harris County, Texas. (A copy of Plaintiff's First Amended Petition is attached hereto as Ex. 3). This case is related to the subject matter of the '384 application and the '808 patent. Nor does the information provided by BCM indicate that BCM alerted the Office to the declaratory judgment action filed in the U.S. District Court for the Southern District of Texas on January 4, 2002, alleging *inter alia*, the invalidity and non-infringement of the '808 patent. (A copy of the Complaint For Declaratory Judgment is attached hereto as Ex. 4). The latter federal case was only recently dismissed on April 7, 2003 (Ex. 5), as a result of BCM's motion to dismiss along with its Covenant Not To Assert The '808 Patent (Ex. 6), which were also not brought to the attention of the Office.

Under 37 C.F.R. § 1.56, applicants and applicants' representatives must disclose (1) the existence of litigation and (2) any material information arising from that litigation related to the

subject matter of the patent application, including, for example, deposition testimony. *See, e.g.*, MPEP 2001.06(c); *Environ Products v. Total Containment, Inc.*, 43 U.S.P.Q. 2d 1288 (E.D. Pa. 1997); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F. Supp.2d 508 (D.N.J. 1999).

The documents BCM recently provided to Clontech from the PTO prosecution include disclosures of some prior art to the Office, but do not include any disclosure of the ongoing litigation and do not include any disclosure of critical admissions that occurred in depositions taken during discovery. The submitted documents also do not include any disclosure of the dismissed litigation and covenant not to assert the '808 patent.

II. THIS PROTEST INVOLVES INFORMATION THAT CANNOT BE ADEQUATELY ADDRESSED WITH REEXAMINATION

Our request for a Protest can only be addressed before issuance because the standard and type of prior art that may be considered will change after issuance. During examination, the Office need only show by a preponderance of the evidence that an application is unpatentable. Once a U.S. patent is issued, any challenge must be supported by clear and convincing evidence. While an issued U.S. patent can be reexamined, a reexamination can only consider patents and printed publications and only address issues arising under sections 102 or 103 of Title 35. BCM should not be permitted to benefit from its refusal to disclose information to the USPTO and to Clontech in a timely manner.

Clontech is bound by a protective order in the ongoing Texas litigation. This protective order bars Clontech from disclosing BCM information and deposition transcripts if BCM has designated them as confidential. BCM has utilized this protective order to designate much of the information disclosed as confidential and has designated all of its witnesses' deposition

testimony as confidential, except that of Dr. Liu. Consequently, Clontech cannot describe any admissions that might be present in other depositions that have occurred, including the depositions of Drs. Elledge and Kreuzer and Ms. Li. Nevertheless, Clontech can disclose that the deposition transcript which BCM did not designate as confidential – that of Dr. Liu -- contains admissions that are material to the patentability of the claims that were provided in the preliminary amendment of October 3, 2002. Claim numbers corresponding to those claims have now been allowed.

The deposition of Dr. Liu admits that at the time of filing of the application that led to the '808 patent (and therefore, necessarily before filing the '384 application therefrom), GST fusion proteins were known and the Cre enzyme was known:

> Q: Okay. Now, GST fusion proteins were known in the art prior to your work, correct?
> A: Correct.
> Q. And the Cre enzyme itself was known in the art prior to your work, correct?
> A. Correct.
> Q. And am I correct in understanding that the Cre recombinies [sic recombinase], the Cre enzyme, its ability to recombine loxP site [sic sites] was also known in the art, correct?
> A. Correct.

(Liu Dep. at 15:23-16:8, Ex. 7).

These admissions appear material to the patentability of for example claims 43, 46, 48, 49, 52-54, 56 and 63 as those claims appear in the Preliminary Amendment that BCM disclosed to Clontech. These claim numbers are those that appear to correspond to the allowed claims on the Notice of Allowability. (Ex. 1).

While Clontech cannot provide information marked confidential to the Office, BCM can provide this information to the PTO. This information can be supplied as part of BCM's Duty of Disclosure under Rule 1.56, or it can be provided in response to a direct request from the Examiner under 37 C.F.R. § 1.105.

The review under 37 C.F.R. § 1.291 represents the PTO's last opportunity to consider information contained in the deposition transcripts. Once the 09/122,384 patent issues, the PTO will not be able to provide any meaningful review of the deposition transcript admissions. As indicated by Assistant Deputy Commissioner Kunin, "[t]he PTO has an obligations to issue patents that meet the statutory requirements for patentability." *Blacklight Power, Inc. v. Rogan*, 295 F.3d 1269, 1271 (Fed. Cir. 2002) (affirming the PTO's decision to cancel issuance of a patent after allowance and after the issue fee was paid). Moreover, the PTO is vested with broad "latitude to withdraw an application from issue without a final determination of unpatentability when the exigencies of time do not allow for such determination." *Id.* at 1272.

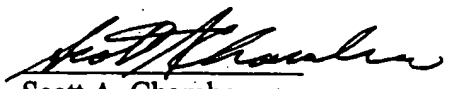
III. THE PTO SHOULD PERMIT THE INITIATION OF A PROTEST OR STAY ISSUANCE OF A PATENT ON THE '384 APPLICATION

The PTO should initiate a Protest, based on the failure of BCM to alert the agency to ongoing litigation related to the '384 application and the failure of BCM to provide the PTO with material deposition admissions. In the alternative, the PTO should stay issuance of the '384 application until the Judge in the Texas 133rd Judicial District Court rules on Clontech's Motion to De-designate Certain Deposition Admissions Material to the Patentability Determination of Baylor Patent Application Claims and permits the PTO Examiner to review the deposition testimony. Clontech is presently preparing a motion to de-designate the transcripts or portions thereof that contain admissions material to the patentability of the '384 application. This motion will be submitted to the Judge, who will determine if this information can be provided to the PTO to permit the PTO to perform its mission.

This Protest has been served upon applicants via their representative in accordance with 37 CFR § 1.248 as well as being filed in duplicate with the PTO. Proof of service is attached as Exhibit 8 hereto.

The U.S. Patent and Trademark Office is hereby authorized to charge any fees that may be required in conjunction with this submission to Deposit Account Number 50-2228.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that on May 20, 2003 I caused to be delivered by fax and FED EX a copy of **PROTEST AGAINST PENDING APPLICATION UNDER 37 C.F.R. § 1.291** and exhibits 1-8 thereto relating to USSN 09/122,384, addressed to the attorney of record in that matter as follows:

Timothy S. Corder
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Phone: (512) 542-8400
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I declare under penalty of perjury that the foregoing is true and correct.

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Paper:	**Summary of Interview; and Postcard**
Inventor:	**Stephen J. Elledge et al.**
Serial No.:	**09/122,384**
Docket No.:	**BAY136/36000/4-10CIP**
Filed:	**July 24, 1998**
Entitled:	**RAPID SUBCLONING USING SITE-SPECIFIC RECOMBINATION**
Date Sent:	**June 27, 2003**

Tim Corder

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